

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

WYETH,

Plaintiff,

v.

IMPAX LABORATORIES, INC.,

Defendant.

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) Civil Action No.: 06-222 JJF  
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**DEFENDANT'S BRIEF IN SUPPORT OF MOTION  
FOR THE APPOINTMENT OF A SPECIAL MASTER  
TO MANAGE DISCOVERY AND RESOLVE DISCOVERY DISPUTES**

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September 22, 2006

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## **I. NATURE AND STAGE OF PROCEEDINGS**

This case for patent infringement was brought by Plaintiff Wyeth to prevent Defendant Impax Laboratories, Inc. ("Impax") from bringing to market a generic version of Wyeth's EFFEXOR<sup>®</sup> XR product, which is a formulation of the anti-depressant medication venlafaxine hydrochloride.<sup>1</sup> (D.I. 1). Discovery commenced in this case on June 23, 2006 when Impax filed its First Set of Requests for Production on Wyeth. Since that time, the parties have become involved in numerous discovery disputes. Thirteen of these disputes are the subject of motions to compel pending before the Court. (D.I. 36, 52). The parties are embroiled in numerous additional discovery disputes, many of which will likely become the subject of future motions to compel. Impax seeks a timely resolution of these disputes because many discovery deadlines are fast approaching. (D.I. 27).

In order to facilitate the resolution of the parties' discovery disputes in a timely and efficient manner without unduly burdening the Court, Impax requests the appointment of a Special Master to manage discovery, to resolve discovery disputes, and to resolve disputes as to whether information qualifies for protection and as to the extent of such protection under any protective order entered in this action or under D. Del. L.R. 26.2.. Impax further requests that the parties' pending motions to compel be referred to the Special Master (D.I. 36, 52).

## **II. SUMMARY OF THE ARGUMENT**

Because a Special Master for discovery rules on non-dispositive, pretrial matters, the Court has broad powers to appoint Special Master for discovery under Federal Rule

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<sup>1</sup> The patents-in-suit are U.S. Patent No. 6,274,171 ("171 patent"), U.S. Patent No. 6,403,120 ("120 patent"), and U.S. Patent no. 6,419,958 ("958 patent"). Wyeth alleges patent infringement under 35 U.S.C. § 271(e)(2)(A) by reason of Impax's submission to the Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 78-057.

of Civil Procedure 53. Moreover, this Court has issued a standing order determining that in intellectual property cases, it is appropriate to appoint Special Masters for discovery to facilitate the prompt and efficient administration of justice. Standing Order of Sept. 15, 2004 at 2, “In Re: Procedures to Govern the Appointment of Special Masters to Hear Discovery Disputes in Intellectual Property Cases.”

The appointment of a Special Master is appropriate in this case because the parties have numerous discovery disputes pending before the Court and numerous additional discovery disputes that may lead to future motions practice. Each party to this action currently has a motion to compel pending before the Court, which together raise thirteen discrete discovery disputes. (D.I. 36, 52). In addition, there are at least seven additional discovery disputes between the parties that may become the subject of future motions to compel. The deadline for the completion of contention interrogatories and document production is October 10, 2006.

The appointment of a Special Master would facilitate the speedy resolution of the parties’ numerous discovery disputes and would avoid unduly burdening the Court. During meet and confer, Wyeth could articulate no reason why the appointment of a Special Master would be inappropriate in this case.

### **III. STATEMENT OF FACTS**

Wyeth initiated this suit for patent infringement against Impax on April 5, 2006. (D.I. 1). Impax answered the Complaint on April 25, 2006. (D.I. 7). Impax served the first discovery requests in this matter when it propounded document requests on Wyeth on June 23. Declaration of Samuel F. Ernst In Support of Defendant’s Motion for the Appointment of a Special Master to Manage Discovery and Resolve Discovery Disputes (“Ernst Decl.”) ¶ 5.

Since discovery commenced, the parties have been involved in numerous discovery disputes. In summary:

- Wyeth refuses to produce redacted documents from its suit against Teva Pharmaceuticals in the District of New Jersey (“Teva Litigation”), in which Wyeth asserted the same patents it asserts in the instant litigation. (D.I. 36 at 1-2).
- Wyeth refuses to produces documents in their native format. (D.I. 36 at 2-3).
- Wyeth insists that Impax pay for the cost of Wyeth’s discovery productions. (D.I. 36 at 3). Wyeth is currently holding its documents hostage, refusing to send copies to counsel for Impax until Impax agrees ahead of time to pay for the cost of production. Ernst Decl., Ex. 1.
- Wyeth refuses to search for and produce documents from its locations outside of the United States. Wyeth undoubtedly has responsive documents at its overseas facilities as one of the clinical studies in support of Wyeth’s NDA for Effexor® XR which is relied upon in the specification of the patents-in-suit – study no. 600B-367-EU – took place in Europe. Moreover, Wyeth has prosecuted foreign equivalents to the patents-in-suit in numerous foreign countries. (D.I. 36 at 4).
- Wyeth has imposed an arbitrary cut-off date of February 10, 2003, more than three years before the lawsuit was filed by Wyeth, and Wyeth will not produce documents created or generated after this date.

These disputes are the subjects of Impax’s pending Motion to Compel, filed on August 10, 2006. (D.I. 36).

In addition to these discovery disputes, the parties have had numerous additional disagreements, many of which may be the subject of motions practice in the future.

These additional disputes include the following:

- Each party has objected to the adequacy of the other party’s responses to contention interrogatories. Ernst Decl., Ex. 2 at 1. Completion of contention interrogatory discovery is due on October 10, at which time Impax anticipates further disputes around this issue.
- Wyeth refuses to produce documents regarding EFFEXOR® other than those “reflecting (1) comparisons between immediate release Effexor® XR, or (2) nausea and/or vomiting in humans associated with immediate release Effexor®.” *Id.*, Ex. 2 at 3.
- Wyeth objects to Impax defining itself in its discovery responses as “the corporate

entity named as defendant in this action, its officers and its agents.” *Id.*, Ex. 2 at 3.

- Wyeth has objected to Impax’s reliance on Federal Rule of Civil Procedure 33(d) in responding to Wyeth’s interrogatory regarding the ingredients of the accused products. *Id.*, Ex. 2 at 4-5.
- Impax has objected to Wyeth’s reliance on Rule 33(d) in response to seven interrogatories propounded by Impax. *Id.*, Ex. 2 at 5.
- Wyeth refuses to produce documents regarding any pre-filing investigation or analysis it conducted to determine whether the accused products infringed even though these documents are directly relevant to Impax’s defense of unclean hands. *Id.*, Ex. 2 at 5.
- Wyeth will not produce “manufacturing records, specifications and analytical methods for venlafaxine hydrochloride itself, stability, toxicology, packaging, quality control, plant layouts and voluminous raw patient data” from its NDA. Ernst Decl., Ex. 3 at 2.

In light of these numerous discovery disputes and the fast-approaching deadline to complete document production and contention interrogatories, Impax requested that Wyeth agree to the appointment of a Special Master in this case during a telephonic meet-and-confer on Friday, September 8. Ernst Decl., ¶ 2. Wyeth refused in a letter sent on September 13, 2006, but gave no reasons for its refusal. Ernst Decl., ¶ 3, Ex. 4 at 2.

Nonetheless, three days later Wyeth filed a Motion to Compel Production of Documents, seeking the production of documents in eight categories, including documents related to Wyeth’s withdrawn claim for willful infringement and documents regarding products that are not accused in this litigation. (D.I. 52).

Accordingly, the parties currently have at least twenty discrete discovery disputes.

#### IV. ARGUMENT

##### A. The Court has broad powers to appoint a Special Master for discovery

The Court has broad powers to appoint a Special Master to manage discovery and to preside over discovery disputes. Fed. R. Civ. P. 53(a)(1)(c). In 2003, Rule 53 was

amended to make clear that, where the Special Master is appointed to address pretrial matters such as discovery, the Court can appoint a Master without the consent of the parties and even if there is no “exceptional condition.” *Id.*; see 9 Moore’s Federal Practice § 53.10[3][a] (“A major purpose of the 2003 amendment to Rule 53 is to reflect actual practice in the courts respecting the appointment of Masters, even though the rule prior to the amendments did not provide for many of the types of appointments the courts made.”) The 2003 amendments to Rule 53 codify a longstanding practice of the courts to appoint Special Masters to handle pretrial discovery matters.<sup>2</sup> As one commentator has noted, “masters may be of particular use in overseeing discovery, especially when there are numerous differences between the parties.” 9 Moore’s Federal Practice § 53.10[3][c][iii][A].

In the specific context of Intellectual Property litigation, this Court has recognized that the appointment of Special Masters to hear discovery disputes is appropriate. In this Court’s Standing Order of September 15, 2004, the Court instituted a panel of Special Masters for the purpose of serving in intellectual property cases. Standing Order of Sept. 15, 2004 at 2, “In Re: Procedures to Govern the Appointment of Special Masters to Hear Discovery Disputes in Intellectual Property Cases” (attached to Ernst Decl. as Ex. 5). The Court stated that the order was “necessary for the prompt and efficient administration of justice in intellectual property cases to, inter alia, manage discovery, conduct hearings on discovery disputes and rule on the same. . . .” *Id.* at 1. The Court also stated that “given this Court’s significant docket of complex intellectual property cases and given that this Court’s magistrate Judge is routinely scheduling hearings and

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<sup>2</sup> See, e.g., *Trans World Airlines, Inc. v. Hughes*, 332 F.2d 602, 611 (2d Cir. 1964) (the trial court properly appointed a Special Master to supervise discovery); *Eggleston v. Chicago Journeymen Plumbers*, 657 F.2d 890, 904 (7th Cir. 1981) (same); *First Iowa Hydro Electric Coop. F.A.E. v. Iowa-Illinois Gas & Elec. Co.*, 245 F.2d 613, 626 (8th Cir. 1957) (same); *Aird v. Ford Motor Co.*, 86 F.3d 216, 218-19 (D.C. Cir. 1996) (same).



mediation calendars six to eight months out, the need to appoint Special Masters to achieve these stated goals is clear.” *Id.*

**B. The appointment of a Special Master will facilitate the speedy resolution of discovery disputes without unduly burdening the Court**

The appointment of a Special Master to manage discovery and handle discovery disputes will facilitate the speedy and efficient disposition of this case. The parties have numerous discovery disputes that are impeding the production of documents and meaningful responses to interrogatories. Thirteen of these disputes are the subject of pending motions to compel. (D.I. 36, 52). In total, the parties are embroiled in at least twenty discovery disputes, many of which may become the subjects of future motions practice. *See* Section III, *supra*.

Because the deadline to complete contention interrogatories, complete discovery production, and disclose trial witnesses is October 10, 2006, the speedy resolution of these discovery disputes is crucial. (D.I. 27 at ¶ 3). For example, the parties’ disagreement over who should pay for the cost of document productions has resulted in Wyeth’s refusal to produce documents until Impax agrees to pay for the cost of Wyeth’s discovery obligations. Ernst Decl., Ex. 1; (D.I. 36 at 1-2). Impax requires an immediate resolution of this dispute, whether in favor of Impax or Wyeth, in order to meet the October 10 deadline for the completion of contention interrogatories.

A Special Master would also relieve the Court of the unnecessary burden of policing the parties’ numerous discovery disputes. In order to facilitate the speedy and efficient resolution of this matter and to preserve precious judicial resources, the Court should appoint a Special Master for discovery.

**C. The Court should refer the pending motions to compel as well as all future discovery disputes to a Special Master.**

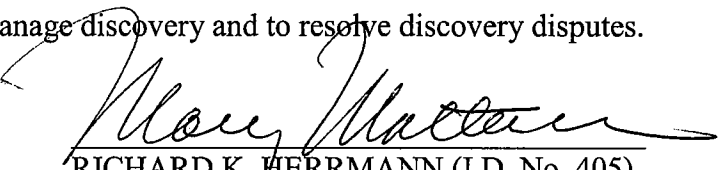
The Court should assign to the Special Master not only future discovery disputes, but also the two pending motions to compel that are before the Court. (D.I. 36, 52). These motions alone treat thirteen discrete discovery disputes between the parties, many

of which should be resolved well before the October 10 deadline for document production and completion of contention interrogatories. In particular, in order to complete contention interrogatories, Impax must receive Wyeth's documents from the Teva Litigation, Wyeth's documents from its foreign facilities, Wyeth's documents generated after February, 2003, and the other documents Wyeth is withholding until Impax agrees to pay for their production. (D.I. 36).

Accordingly, the Court should refer the pending motions to compel to the Special Master in addition to future discovery disputes.

#### V. CONCLUSION

For the foregoing reasons, Impax respectfully requests that the Court appoint a Special Master in this case to manage discovery and to resolve discovery disputes.



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Dated: September 22, 2006

**CERTIFICATE OF SERVICE**

I hereby certify that on the 22<sup>nd</sup> day of September, I electronically filed the foregoing document, **DEFENDANT'S BRIEF IN SUPPORT OF MOTION FOR THE APPOINTMENT OF A SPECIAL MASTER TO MANAGE DISCOVERY AND RESOLVE DISCOVERY DISPUTES**, with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

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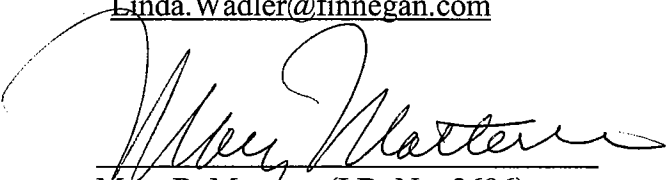
Additionally, I hereby certify that on the 22<sup>nd</sup> day of September, 2006, the foregoing document was served as indicated on the following:

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